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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,364	08/07/2000	John Fikes	18623014710	3960

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/29/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/633,364

Applicant(s)

FIKES ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 114, 117, 121-131, 133-137, 139, 140 and 211-229 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 124, 135-137, 139, 140, 215 and 225-228 is/are rejected.
- 7) ☒ Claim(s) 114, 117, 121-123, 125-131, 133, 134, 211-214, 216-224, and 229 is/are objected to.
- 8) ☒ Claim(s) 114, 117, 121-131, 133-137, 139, 140 and 211-229 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

### **DETAILED ACTION**

1. The election with traverse filed July 29, 2002 in Paper No. 12 is acknowledged and has been entered.
2. The amendment filed July 29, 2002 in Paper No. 12 is acknowledged and has been entered. Claims 1-37 have been canceled. Claims 38-210 have been added.
3. The amendment filed November 4, 2002 in Paper No. 16 is acknowledged and has been entered. Claims 38-113, 115, 116, 118-120, 132, 138, and 141-210 have been canceled. Claims 130, 134, and 140 have been amended. Claims 211-229 have been added.
4. Claims 114, 117, 121-131, 133-137, 139, 140, and 211-229 are pending in the application and are currently under prosecution.

### ***Election/Restrictions***

5. Applicants' grounds of traversal of the restriction requirement set forth in the Office action mailed January 29, 2002 (Paper No. 8) have been carefully considered but have not been found persuasive. Applicants have argued the requirement is improper because the claims are drawn to peptides of less than 15 amino acids comprising an amino acid sequence selected from a Markush group consisting of six amino acid sequences. Accordingly, Applicants have asserted that the members of the Markush group are sufficiently few that an examination of the entire claim can be made without burden, which Applicants have noted the MPEP states would render the requirement improper, even though the inventions are distinct. Contrary to Applicants' assertions, however, the examination of the entire claim reciting the Markush group would unduly burden the examiner, because the searches that would be need be performed to examine the different inventions are not co-extensive. The search required for the examination of any one invention is not the same as that which would be required for

the examination of any other invention. For this reason, the restriction requirement is deemed proper and therefore made FINAL.

### ***Specification***

6. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

For example, the trademarks MICROMEDIC and INVITROGEN are improperly used on pages 82 and 85 in lines 28 and 32, respectively.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., <sup>TM</sup>, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

### ***Lack of Compliance with the Requirements of 37 CFR §§ 1.821-1.825***

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice to Comply. Applicants must comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825) before the application can be further examined under 35 U.S.C. §§ 131 and 132.

An example of a sequence that is of sufficient length to require compliance with the rules set forth under 37 CFR §§ 1.821-1.825 can be found on page 54. It is noted that although this deficiency was corrected in the amendment filed July 2, 2001, the amendment filed November 4, 2002 restored the deficiency.

Applicants are required to correct this deficiency and any others; and if necessary to do so, Applicants are required to submit substitute copies of the sequence listing and a statement that both copies are the same and that no new matter has been added, as indicated on the attached Notice to Comply.

Applicant is given the same period of time within which to reply to this Office action to correct any deficiencies. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Applicants are requested to return a copy of the attached Notice to Comply with the response.

### ***Claim Objections***

8. Claims 224 and 229 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 134. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claim 229 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of claim 224 from which it depends. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

10. Claim 114 and any claim that depends therefrom is objected to because claim 14 is drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 124, 135-137, 139, 140, 215, and 225-228 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 124 is indefinite because the claim is not properly punctuated with a period.

Claims 135-137, 139, 140, and 225-228 are indefinite because claims 135 and 225 recite the limitation "and one or more second peptides". Recitation of the limitation renders the claim indefinite because if the peptide of claim 117 is fused to more than one other peptide, it is inappropriate to refer to each of the other peptides as "second peptides", and accordingly one skilled in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 225 to replace "second" with "other" can obviate this ground of rejection.

Claim 215 contains the trademark/trade name PADRE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The metes and bounds of the invention are uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the T helper peptide and, accordingly, the identification/description is indefinite.

### **Conclusion**

13. No claims are allowed.

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14. The art made of record and not relied upon is considered pertinent to Applicants' disclosure. WO 9420127-A teaches an antigenic fragment of polypeptide that consists of the amino acid sequence set forth in SEQ ID NO: 6827. Bodey, et al and Bocchia, et al review the state of the art.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
January 16, 2003

  
ANTHONY C. CAPUTA  
ASSISTANT PATENT EXAMINER  
TECHNOLOGY CENTER 1642

## Notice to Comply

Application No.

09/633,364

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

FIKES ET AL.

Art Unit

1642

### NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: If necessary to comply, Applicants are required to submit substitute copies of the sequence listing and the statement indicated below.

#### Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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